DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR BENEFICIARY CHOICES

September 29, 2006

Memorandum To: All Part D Sponsors

Subject: HPMS Q & A - Clarification regarding Part D drug definition

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

The following question and answer will be posted to the Frequently Asked Questions Database on the CMS website at http://questions.cms.hhs.gov.

Q: Are inhaler supplies or accessories, such as Metered Dose Inhaler (MDI) actuators or chambers, included within the definition of a Part D drug and available for reimbursement by a Part D Sponsor?

A: Yes. As long as the MDI accessory is approved by FDA to be packaged with the drug and is included in the final packaging by the manufacturer.

The definition of a Part D drug includes a drug that is described in section 1927(k)(2)(A)(i) of the Social Security Act. This section specifically defines a "covered outpatient drug" as one that is approved for safety and effectiveness as a prescription drug under section 505 of the FD&C Act, which requires submission by the manufacturer of a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA).

In general, as it relates to MDIs, Dry Powder Inhalers (DPIs), or Nasal Spray Inhalers (NS), if the associated accessories are included on the NDA or ANDA for the drug product and included on the drug product's approved package insert, then when specifically packaged with the drug product itself, the associated accessories are eligible to meet the definition of Part D drug. However, we reserve the right to revisit this policy on a product-by-product basis to account for new product and the accompanying regulatory environment to ensure the appropriate use of these accessories.

Additionally, if the accessories (i.e., actuator, chamber) are sold separately or are not included on the drug product's NDA or ANDA, they would not meet the definition of a Part D drug.

It is important to clarify that for inhaled insulin, the inhalation supplies may be sold separately. We stated in the preamble to the January 28, 2005 final rule implementing provisions of Part D (70 FR 4194) that we were interpreting the term ''medical supplies associated with the injection of insulin'' in section1860D–2(e) of the Act as comprising syringes, needles, alcohol swabs, gauze, and insulin delivery devices not otherwise covered by Part B…". Accordingly, those inhalation supplies either packaged with the insulin or packaged separately, when used to deliver the inhaled form of insulin, are eligible to meet the definition of a Part D drug.

Part D sponsors are reminded that they must perform coverage determinations for MDIs, DPIs, or NSs, as they do for any other Part D drugs, and may apply appropriate drug utilization management tools, consistent with existing Part D laws, regulations and guidance.

Please contact Greg Dill at (312) 353-1754 if you have any questions about this guidance.